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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/085,656	02/27/2002	Edward S. Yeung	215401	8655

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LEYDIG VOIT & MAYER, LTD
TWO PRUDENTIAL PLAZA, SUITE 4900
180 NORTH STETSON AVENUE
CHICAGO, IL 60601-6780

EXAMINER	
OLSEN, KAJ K	

ART UNIT	PAPER NUMBER
1753	

DATE MAILED: 07/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/085,656	YEUNG ET AL.	
	Examiner	Art Unit	
	Kaj K Olsen	1753	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-32 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-32 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. All the independent claims specify the use of a non-ionic monomeric surfactant. However, the monomeric surfactant in question is further specified to be a polymer itself (see claims 2 and 9 as examples). It is confusing to identify the presence of a polymer by the term "monomer".

4. In claims 9, 17, applicant uses abbreviations to represent various ethers. The names of the materials represented by these abbreviations should be explicitly written out in the claims.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-5, 7, 10, 12-14 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Magnusdottir

et al (Electrophoresis 1998, 19, pp. 1699-1703) with or without evidence from Rill et al (J. Chromatography A 817 (1998), pp. 287-295).

7. Magnusdottir discloses a method of carrying out size separation that comprises providing a sample solution having target analytes, providing a sieving medium in a receptacle (a capillary) where the sieving material is a non-ionic material having the general formula B-A-B using the claim nomenclature. See the abstract, and sections 2.1-2.3. Although B-A-B is differs from the claimed formula B-A, the claims are constructed with open language (i.e. they comprise a material with the formula B-A), there is nothing in the claims that prevents other groups from being connected to the B-A unit. The B-A-B unit of Magnusdottir was present in solvent concentrations for forming self-assembled micelles having a large enough aggregation number that size separation can be effected thereby resolving the target analyte. See fig. 3 and 4 and section 3 of the reference. Although the material of Magnusdottir is a polymer, it would appear to read on the applicant's confusing interpretation of "monomeric" giving the claim language its broadest reasonable interpretation (see 112 rejection above). With respect to the triblock polymer of Magnusdottir being a "surfactant", it would appear that any material that comprises both hydrophilic and hydrophobic units would inherently constitute a surfactant even when the material doesn't terminate in hydrophilic and hydrophobic units. This is evidenced by Rill, which teaches that similar triblock polymers (i.e. Pluronic polymers) are known in the art as being surfactants. See Rill et al, p. 288, first column.

8. The material of Magnusdottir reads on the defined n-alkyl polyoxyethylene ether.

9. With respect to the specified aggregation number, although Magnusdottir does not specify, because the reference discloses the formation of a gel state and sieving material, it inherently has an aggregation number of at least 100, 1000, and 10000. Alternatively, finding an aggregation number to arrive to arrive at the desired level of sieving capability for the molecular weight of analyte in question requires only routine skill in the art..

10. With respect to adjusting the concentration of the surfactant, see section 2.3.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. Claims 6, 21-23 and 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Magnusdottir in view of Liu et al (ACS Symposium Series (2000), 765, pp. 2-20).

13. Magnusdottir set forth all the limitations of the claims, but did not explicit recite the use of temperature to control the micelle aggregation. Liu teaches in an alternate micelle based sieving medium that temperature can be utilized for controlling the properties of the gel-like material (p. 16), which would inherently include the aggregation number for the micelle. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Liu for the method and apparatus of Magnusdottir because temperature is a convenient means for loading the gel-like material into and out of the capillaries.

14. Claims 8, 15, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Magnusdottir in view of Menchen et al (USP 5,290,418).

15. Claims 31 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Magnusdottir and Liu in view of Menchen '418.

16. With respect to claim 8, the reference set forth all the limitation of the claim, but did not explicitly recite the presence of a denaturant. Menchen '418 sets forth that adding denaturant to a sieving matrix is known in the art (col. 14, lines 46-50). It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Menchen '418 for the method of Magnusdottir and add a denaturant to the sieving matrix in order to ensure the sample is sufficiently denatured. With respect to the denaturant adjusting the aggregation, that would appear to be an inherent property of adding a known material to micelle based sieving matrix. Finding a new reason for doing what was already old in the art is not a patentable distinction.

17. With respect to claims 15, 16, 31 and 32, the reference or reference set forth all the limitations of the claims, but did not explicitly recite the use of fluorescence or UV for the detection. However, both of these techniques are notoriously old in the art. In particular, Menchen '418 teaches that both detection means are old in the art. See paragraph bridging col. 16 and 17. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Menchen '418 for the apparatus of Magnusdottir (or Magnusdottir and Liu) because the use of known detection schemes for existing capillary electrophoresis apparatuses requires only routine skill in the art.

18. Claims 11, 15, 19 and 20 rejected under 35 U.S.C. 103(a) as being unpatentable over Magnusdottir in view of Yeung et al (USP 5,582,705).

19. Claims 24, 25 and 29-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Magnusdottir and Liu in view of Yeung.

20. With respect to claims 11, 19, 20, 24, 25, 29 and 30, the reference(s) set forth all the limitations of the claim, but did not explicitly recite the use of a plurality of capillaries for the analysis. Yeung teaches in an alternate electrophoresis device that the use of a plurality of capillaries allows a number of analyses to occur simultaneously, thereby increasing the rate of sample analysis. See col. 7, lines 20-32. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Yeung for the method and apparatus of Magnusdottir (or Magnusdottir and Liu) in order to increase the rate of analysis. With respect to claims 15 and 31, Yeung also teaches the use of laser induced fluorescence in known in the art (col. 25, lines 9-34), and the use of known detection schemes for an existing method or apparatus requires only routine skill in the art.

Allowable Subject Matter

21. Claims 9 and 17 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

22. The following is a statement of reasons for the indication of allowable subject matter: the prior art does not disclose nor render obvious all the limitations of claims 2 and 14 and further comprising the specified surfactants. Although the examiner

acknowledges that the set forth class of polyoxyethylene ethers are known from the electrokinetic chromatography art (see Clothier et al), there is no indication in this reference that the aggregated ethers have aggregated to an extant to meet the claim limitation that they provide or are a sieving medium capable of resolving analytes by size.

Conclusion

23. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Rill (Chromatographia) and Munchen '365 disclose alternate sieving media.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kaj Olsen whose telephone number is (571) 272-1344. The examiner can normally be reached on Monday through Thursday from 6:30 A.M. to 4:00 P.M. and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen, can be reached on 571-272-1342. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you

have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kaj Olsen Ph.D.
Primary Examiner
AU 1753
June 25, 2004